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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 40567 09/610,891 07/06/2000 James McArthur 6712 EXAMINER 7590 01/30/2006 YU, MISOOK Steven B Kelber Esq Piper Rudnick LLP ART UNIT PAPER NUMBER 1200 19th Street N W

1642
DATE MAILED: 01/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)	Applicant(s)	
Office Action Summary	09/610,891	MCARTHUR ET AL.		
	Examiner	Art Unit		
	MISOOK YU, Ph.D.	1642		
The MAILING DATE of this communication	appears on the cover sheet with	h the correspondence ac	ddress	
Period for Reply				
A SHORTENED STATUTORY PERIOD FOR REI WHICHEVER IS LONGER, FROM THE MAILING - Extensions of time may be available under the provisions of 37 CFR after SIX (6) MONTHS from the mailing date of this communication If NO period for reply is specified above, the maximum statutory per - Failure to reply within the set or extended period for reply will, by sta Any reply received by the Office later than three months after the may earned patent term adjustment. See 37 CFR 1.704(b).	B DATE OF THIS COMMUNIC R 1.136(a). In no event, however, may a replication will apply and will expire SIX (6) MONT atute, cause the application to become ABA	ATION.  Oly be timely filed  HS from the mailing date of this of NDONED (35 U.S.C. § 133).	,	
Status				
1) Responsive to communication(s) filed on 25	5 February 2005 and 11 July 2	005.		
	his action is non-final.	<u> </u>		
3) Since this application is in condition for allow		rs, prosecution as to the	e merits is	
closed in accordance with the practice unde	•	•		
Disposition of Claims				
4) Claim(s) <u>35-40 and 44-52</u> is/are pending in	the application.			
4a) Of the above claim(s) <u>48-52</u> is/are withd	• •			
5) Claim(s) is/are allowed.				
6) Claim(s) <u>35,37,38 and 40</u> is/are rejected.				
7) Claim(s) <u>36,39 and 44-47</u> is/are objected to	) <b>.</b>			
8) Claim(s) are subject to restriction and				
Application Papers				
9) The specification is objected to by the Exam	iner.			
10) The drawing(s) filed on is/are: a) a		v the Examiner.		
Applicant may not request that any objection to t	• •	•		
Replacement drawing sheet(s) including the con		• •	FR 1.121(d).	
11) ☐ The oath or declaration is objected to by the	Examiner. Note the attached	Office Action or form P	TO-152.	
Priority under 35 U.S.C. § 119				
12) ☐ Acknowledgment is made of a claim for fore a) ☐ All b) ☐ Some * c) ☐ None of:	ign priority under 35 U.S.C. §	119(a)-(d) or (f).		
1. Certified copies of the priority docume	ents have been received.			
2. Certified copies of the priority docume		plication No		
3. Copies of the certified copies of the p		-	Stage	
application from the International Bure	eau (PCT Rule 17.2(a)).		-	
* See the attached detailed Office action for a l	list of the certified copies not re	eceived.		
Attachment(s)				
) Notice of References Cited (PTO-892)	4) Interview Su			
<ul> <li>Provided the state of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>Provided the state of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>Provided the state of Draftsperson (PTO-1449)</li> </ul>		Mail Date ormal Patent Application (PT0	O-152)	
Paper No(s)/Mail Date	6) Other:		- · <b></b> ,	

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### **DETAILED ACTION**

## Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 25 February 2005 and 11 July 2005 has been entered.

Claims 48-59 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) from the examination for reason of record. Claims 35-40 and 44-52 are pending. Claims 35-40 and 44-47 are examined on merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

This Office action contains new grounds of rejections.

## Specification, Maintained

The specification remains objected because the trademark GVAX is not be accompanied by the generic terminology. It is not clear what the single bracket surrounding GVAX means in the amendment to the specification filed on 15 July 2005 Adding the generic terminology for the trademark GVAX at its first occurrence would obviate this objection.

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# Claim Rejections - 35 USC § 103, Withdrawn

The rejection of claims 35-39 and 44-47 under 35 U.S.C. 103(a) as being unpatentable over Sanda et al., J Urol. 1994 Mar;151(3):622-8, in view of Savarese et al., Prostate. 1998 Feb 1;34(2):80-91, and further in view of Thomas et al., Hum Gene Ther. 1998 Apr 10;9(6):835-43 is withdrawn because of applicant's persuasive arguments.

# Claim Rejections - 35 USC § 102

Claims 35, 37, 38 and 40 rejected under 35 U.S.C. 102(b) as being anticipated by Wollin et al., Radiother Oncol. 1989 Jul;15(3):285-93, abstract only with this Office action. The full journal would be provided when available.

Claims 35, 37, 38 and 40 are drawn to a composition comprising a GM-CSF-expressing proliferation-incompetent PC3, or DU145.

Wollin et al., teach a composition comprising irradiated PC3, or DU145.

According to either Lang et al., International Journal of Cancer 59 (2): p235-241 1994 abstract only, or Rockhlin et al., Anticancer Research (ANTICANCER RES.) (Greece) 1996, 16/2 (557-563 abstract only, both PC3, or DU145 expresses GM-CSF. As for the limitation "proliferation-incompetent", the specification at page 9 lines 12-15 discloses "proliferation- incompetent" refers to cells which are unable to divide, but which express genes encoding tumor associated proteins, and the instant specification at page 64, line 28 for example, discloses "irradiated" prostate cell lines before administration. Thus, the instant specification as a whole teaches that irradiation makes tumor cells "proliferation-incompetent". As for in vivo immune responses with the various molecular

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weights, the instant claim 35 says that a composition comprising irradiated PC3, or DU145 has the ability to produce such response.

### Conclusion

The objected claims are objected because they depend on the rejected base claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MISOOK YU, Ph. Primary Examiner Art Unit 1642